in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response, Applicants have canceled the pending Claims and added new Claims 26-59. Applicants note that the Examiner admitted (page 2 of the Office Action), that the specification is enabling for treating prostate cancer. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection under 35 U.S.C. 112.

REJECTION UNDER 35 U.S.C. 112, Second paragraph:

In the Office Action, the Examiner rejected the Claims under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In response, Applicants have canceled the pending Claims and added new Claims 26-59. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection under 35 U.S.C. 112 second paragraph.

CLAIM OBJECTIONS:

In the Office Action, the Examiner rejected the Claims under 37 U.S.C. 1.75(c) as allegedly being of improper dependent form.

In response, Applicants have canceled the pending Claims and added new Claims 26-59. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection under 37 U.S.C. 1.75(c).

OBVIOUS-TYPE DOUBLE PATENTING REJECTION

In the Office Action, the Examiner provisionally rejected the Claims under the judicially created doctrine of obvious-type double patenting over the Claims of US Patent No. 6,265,448 and copending applications Us Serial Nos 09/306,958; 09/531,472; 09/660,184; 09/660,191; and 09/660,197.

In response, Applicants upon an indication by the Examiner of allowable subject matter, will file a terminal disclaimer. Accordingly, Applicants respectfully request the Examiner to hold the obvious-type double patenting rejection in abeyance until such time.

REJECTION UNDER 35 U.S.C. 103:

In the Office Action, the Examiner rejected the Claims under 35 U.S.C. 103(a) as being allegedly unpatentable over Toivola et al. in view of Swindell et al. and DeGregorio et al.

In response, Applicants traverse the Examiner's rejection as allegedly being unpatentable over Toivola et al. in view of Swindell et al. and DeGregorio et al. Applicants maintain that none of the references either alone or in combination render obvious the claimed invention.

None of the prior art cited teaches the subject matter. Specifically, none of the cited references alone or in combination disclose or teach methods of suppressing or inhibiting latent prostate cancer or treating a subject with prostate cancer comprising the steps of administering to the subject, a pharmaceutical preparation comprising a selective estrogen receptor modulator (SERM). Further, none of the cited references alone or in combination disclose or teach methods of suppressing or inhibiting pre-malignant lesions of prostate cancer or treating a subject with pre-malignant lesions of prostate cancer comprising the steps of administering to the subject a pharmaceutical composition comprising an selective estrogen receptor modulator (SERM). Thus, since none of the references disclose or teach methods of suppressing or inhibiting latent prostate cancer; and suppressing or inhibiting pre-malignant lesions of prostate cancer or treating a subject with pre-malignant lesions of prostate cancer none of the reference can render obviosu Applicants' invention.

Toivola et al, Swindell, Jalonen et al. and DeGregorio et al. are devoid of any teaching as to methods of suppressing or inhibiting latent prostate cancer; and suppressing or inhibiting pre-malignant lesions of prostate cancer or treating a subject with pre-malignant lesions of prostate cancer. Moreover, the subject matter of Jalonen et al., DeGregorio, and Swindell are directed to completely different compounds. For example, Swindell which the Examiner relies on, is directed to taxanes which are in a completely different class of compounds as compared to the SERMS of Applicants' invention.

Applicants maintain that contrary to the Examiners' assertion, there is no motivation to one skilled in the art to combine any of the cited references, since none of them teach methods of suppressing or inhibiting latent prostate cancer; and suppressing or inhibiting pre-malignant lesions of prostate cancer or treating a subject with pre-malignant lesions of prostate cancer. Therefore, the above cited references do not render and could not render obvious Applicants' invention. Accordingly, Applicants respectfully requests the Examiner to reconsider and withdraw the rejection under 35 U.S.C. 103.

Based on the foregoing, Applicants request allowance of the claims. Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below.

If any fee is due for filing this Amendment, the undersigned Attorney hereby authorizes the United States Patent and Trademark Office to charge such fee to Deposit Account No. 05-0649.

Respectfully Submitted,

Dated: August 21, 2002

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please cancel claims 1-25 without prejudice or disclaimer.

Please add new Claims 26- 59 as follows:

–26. (New) A method of suppressing or inhibiting latent prostate cancer of a subject comprising: administering to the subject, a pharmaceutical preparation comprising a selective estrogen receptor modulator (SERM); and a pharmaceutically acceptable salts, esters, or N-oxides, or mixtures thereof, thereby suppressing or inhibiting latent prostate cancer of the subject.

27. (New) A method of treating a subject with prostate cancer comprising: administering to the subject, a pharmaceutical preparation comprising a selective estrogen receptor modulator (SERM); and a pharmaceutically acceptable salts, esters, or N-oxides, or mixtures thereof, thereby treating the subject with prostate cancer.

28. (New) The method of Claims 26 or 27, wherein the subject has a precancerous precursors of prostate adenocarcinoma.

29. (New) The method of Claim 28, wherein the precancerous precursors of prostate adenocarcinoma is prostate intraepithelial neoplasia (PIN).

30. (New) The method according to Claim 28, wherein said subject has benign prostatic hyperplasia, or an abnormally high level of circulating prostate specific antibody (PSA).

31. (New) The method according to any of Claims 26 or 27, wherein said pharmaceutical preparation further comprises a pharmaceutically acceptable carrier

32. (New) The method according to Claim 31, wherein said carrier is selected from the group consisting of a gum, a starch, a sugar, a cellulosic material, or mixtures thereof.

33. (New) The method according to any of Claims 26 or 27, wherein said selective estrogen receptor modulator (SERM) is administered subcutaneously, orally, intravenously, intraarterially, intramuscularly, or topically.

34. (New) The method according to Claim 33, whereby said subcutaneous administration is by implanting in said subject a pellet containing said pharmaceutical preparation.

35. (New) The method according to Claim 34, wherein said pellet provides for controlled release of said pharmaceutical preparation over a period of time.

36. (New) The method according to Claim 33, whereby said intravenous, intra-arterial, or intramuscular administration is by intravenously, intraarterially, or intramuscularly injecting in said subject said pharmaceutical preparation in a liquid form.

37. (New) The method according to Claim 36, whereby said oral administration is by orally administering to said subject in a liquid or solid preparation containing said pharmaceutical preparation.

38. (New) The method according to Claim 37, whereby said topical administration is by applying to skin surface of said subject said pharmaceutical preparation.

39. (New) The method according to Claim 38, wherein said pharmaceutical preparation is selected from the group consisting of a pellet, a tablet, a capsule, a solution, a suspension, an emulsion, an elixir, a gel, a cream, and a suppository.

40. (New) The method according to Claim 39, wherein said suppository is a rectal suppository or a urethral suppository.

41. (New) The method according to Claim 38, wherein said pharmaceutical preparation is a parenteral formulation.

42. (New) The method according to claim 41, wherein said parenteral formulation comprises a liposome comprising a complex of said an selective estrogen receptor modulator (SERM) and a cyclodextrin compound.

43. (New) A method of suppressing or inhibiting pre-malignant lesions of prostate cancer of a subject comprising: administering to the subject a pharmaceutical composition comprising an selective estrogen receptor modulator (SERM); and a pharmaceutically acceptable salts, esters, or N-oxides, or mixtures thereof, thereby suppressing or inhibiting the pre-malignant lesions of prostate cancer of the subject.

44. (New) A method of treating a subject with pre-malignant lesions of prostate cancer comprising the steps of: administering to the subject, a pharmaceutical composition comprising an selective estrogen receptor modulator (SERM); and a pharmaceutically acceptable salts, esters, or N-oxides, or mixtures thereof, thereby treating the subject with pre-malignant lesions of prostate cancer.

45. (New) The method of any of Claims 43 or 44, wherein the pre-malignant lesion is a precancerous precursors of prostate adenocarcinoma.

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46. (New) The method of Claims 45, wherein the precancerous precursors of prostate adenocarcinoma is prostate intraepithelial neoplasia (PIN).

47. (New) The method of Claim 46, wherein the prostate intraepithelial neoplasia is high prostate intraepithelial neoplasia (HPIN).

48. (New) The method according to any of Claims 43 or 44, wherein said pharmaceutical composition further comprises an acceptable carrier or diluent.

49. (New) The method according to Claim 48, wherein said carrier is selected from the group consisting of a gum, a starch, a sugar, a cellulosic material, or mixtures thereof.

50. (New) The method according to any of Claims 43 or 44, wherein said selective estrogen receptor modulator (SERM) is administered subcutaneously, orally, intravenously, intraarterially, intramuscularly, or topically.

51. (New) The method according to Claim 50, whereby said subcutaneous administration is by implanting in said subject a pellet containing said pharmaceutical composition.

52. (New) The method according to Claim 50, wherein said pellet provides for controlled release of said pharmaceutical preparation over a period of time.

53. (New) The method according to Claim 50, whereby said intravenous, intra-arterial, or intramuscular administration is by intravenously, intraarterially, or intramuscularly injecting in said subject said pharmaceutical composition in a liquid form.

54. (New) The method according to Claim 50, whereby said oral administration is by orally administering to said subject in a liquid or solid preparation containing said pharmaceutical composition.

55. (New) The method according to Claim 50, whereby said topical administration is by applying to skin surface of said subject said pharmaceutical composition.

56. (New) The method according to any of Claims 43 or 44, wherein said pharmaceutical composition is selected from the group consisting of a pellet, a tablet, a capsule, a solution, a suspension, an emulsion, an elixir, a gel, a cream, and a suppository.

57. (New) The method according to Claim 56, wherein said suppository is a rectal suppository or a urethral suppository.

58. (New) The method according to any of Claims 43 or 44, wherein said pharmaceutical composition is a parenteral formulation.

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59. (New) The method according to Claim 58, wherein said parenteral formulation comprises a liposome comprising a complex of said an selective estrogen receptor modulator (SERM) and a cyclodextrin compound.--